IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

DAWANNA ROBERTSON and STEPHEN ROBERTSON, Individually and as Parents and Next Friends of SYDNEE ROBERTSON, a minor child, JEFFREY TEEL and PAIGE TEEL, JULIE HORN, Individually, and as Administratrix of the ESTATE OF DON E. HORN, DEBORAH BUTLER, and WESLEY BUTLER, DOROTHY WYNN, MARK GAFFNEY, BEVERLY ANN HARRIS and LESTER HARRIS, PATRICIA ANNE YOUNG, SHARON LEA MORGAN, and RONALD EUWELL WATKINS, Individually, and as the Co-Trustees of the ELLA OLGIA WATKINS REVOCABLE TRUST, SHIRLEY ROGERS and BOB ROGERS, PATRICK ADMIRE, as Personal Representative of the Estate of KATHLEEN C. WEDDLE, Deceased, PHYLLIS FRIESNER, as Personal Representative of the Estate of JAMES F. FRIESNER, Deceased, and SANDRA GRUBBS, as Administratrix of the Estate of TERRELL GRUBBS, Deceased.

PLAINTIFFS,

vs.

J. MICHAEL MCGEE, M.D., F.A.C.S., DANIEL C. PLUNKET, MD, LINDA ANDREWS, R.N., KEVIN DONOVAN, M.D., LARRY EVANS, J.D., GLENN LYTTE, M.D., KATHLEEN RAYMAN, PH.D., R.N., TERRY MOORHEAD, R.PH., JULIE WARRECK, M.D., ANTONIO DELEON, JR., M.D., PAM PRICE HOPKINS, PH.D., R.N., MICHAEL BOYLE, M.D., STEVE BUCK, EDWARD WORTHAM, JR., PH.D, DAVID L. BOREN, HAROLD L. BROOKS, M.D., THOMAS BROUGHAN, M.D., ST. JOHN MEDICAL CENTER, HOAG CANCER CENTER, PATRICK GOMEZ, M.D., CANCER & HEMATOLOGY CENTER and IMMUNEX CORPORATION

DEFENDANTS.

Case No.: 01-CV-60 H(M) ~~01CV00GOH(M)~~

JURY TRIAL DEMANDED

FILED
MAR 30 2001
Phil Lombardi, Clerk
U.S. DISTRICT COURT

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FIRST AMENDED COMPLAINT

COME NOW, the Plaintiffs above named, and for their complaint and causes of action against the Defendants, allege and state:

PARTIES

1. Plaintiff Dawanna Robertson is a citizen of the United States and the State of Oklahoma and is a resident of the County of Okmulgee.

2. Plaintiff Stephen Robertson is a citizen of the United States and the State of Oklahoma and is a resident of the County of Okmulgee. Stephen Robertson is the husband of Dawanna Robertson.

3. Plaintiff Sydnee Robertson is a minor and a citizen of the United States and the State of Oklahoma and is a resident of the County of Okmulgee. This action is brought on behalf of Sydnee Robertson by her mother, Dawanna Robertson.

4. Plaintiff Jeffrey Teel is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa.

5. Plaintiff Paige Teel is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa. Paige Teel is the wife of Jeffrey Teel.

6. Plaintiff, Julie Horn, Individually and as Administratrix of the Estate of Don Horn, Deceased, is a citizen of the United States and the State of Oklahoma, and is a resident of Muskogee County, and is formerly a resident of the State of Maryland, wherein the Estate of Don Horn, Deceased was probated. Julie Horn was the wife of Don Horn.

7. Plaintiff Deborah Butler is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa.

8. Plaintiff Wesley Butler is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa. Wesley Butler is the husband of Deborah Butler.

9. Plaintiff Dorothy Wynn is a citizen of the United States and the State of Oklahoma and is a resident of the County of Muskogee.

10. Plaintiff Mark Gaffney is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa.

11. Plaintiff Beverly Ann Harris is a citizen of the United States and the State of Missouri.

12. Plaintiff Lester Harris is a citizen of the United States and the State of Missouri. Lester Harris is the husband of Beverly Ann Harris.

13. Plaintiff, Patricia Anne Young, Sharon Lea Morgan, and Ronald Euwell Watkins, Individually and as the Co-Trustees of the Ella Olgia Watkins Revocable Trust, are citizens of the United States and the State of Oklahoma, and are residents of Tulsa County. That Ella Olgia Watkins, Deceased, is formerly a resident of the State of Oklahoma and Tulsa County.

14. Plaintiff, Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle, Deceased, is a citizen of Tulsa County, State of Oklahoma.

15. Plaintiff, Phyllis Freisner, as Personal Representative of the Estate of James F. Freisner, Deceased, is a citizen of Tulsa County, State of Oklahoma.

16. Plaintiff, Sandra Grubbs, as Administratrix of the Estate of Terrell Grubbs, Deceased, is a citizen of the State of Florida.

17. Defendant J. Michael McGee, M.D., F.A.C.S., was an Assistant Professor of Medicine, Division of Surgery, University of Oklahoma Health Sciences Center-Tulsa ("OUHSC-

T"), is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa.

18. Defendants Daniel C. Plunket, MD, Linda Andrews, R.N., Kevin Donovan, M.D., Larry Evans, J.D., Glenn Lytte, M.D., Kathleen Rayman, Ph.D., R.N., Terry Moorhead, R.PH., Julie Warreck, M.D., Antonio deLeon, Jr., M.D., Pam Price Hopkins, Ph.D., R.N., Michael Boyle, M.D., and Steve Buck (collectively "IRB Defendants") are individual citizens of the United States and the State of Oklahoma and believed to be residents of the County of Tulsa. Each was a member of the Institutional Review Board ("IRB") of OUHSC-T ("Tulsa IRB"). Defendant Antonio deLeon is also Chairman of the St. John Medical Center IRB. Defendant Kevin Donovan is also the Chief Bioethicist who consulted with the Tulsa IRB and OUHSC-T.

19. Defendant Edward Wortham, Jr., PhD, the former Director of the Office of Research at the OUHSC-T, is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa. Dr. Wortham was responsible for supervising all research conducted at OUHSC-T, in general, and supervising the work of the Tulsa IRB, in particular.

20. Defendant David L. Boren, President of the University of Oklahoma, is a citizen of the United States and the State of Oklahoma. Senator Boren presides over the Board of Regents which conducts the affairs of the University of Oklahoma.

21. Defendant Harold L. Brooks, M.D., the former Dean of the Oklahoma University College of Medicine in Tulsa, is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa. Dr. Brooks was in effect the chief operating officer of OUHSC-T and was responsible for the manner in which it conducted its affairs.

22. Defendant Thomas Broughan, M.D., the Chairman of the Department of Surgery at OUHSC-T, is a citizen of the United States and the State of Oklahoma and is a resident of the County of Tulsa. Dr. Broughan is the supervisor of Dr. McGee.

23. The IRB Defendants and defendants Dr. McGee, Dr. Brooks, Dr. Broughan, Dr. Wortham and Senator Boren (collectively "State Actor Defendants") at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

24. Defendant St. John Medical Center is believed to be a corporation and citizen of Oklahoma with an address at 1923 South Utica Avenue, Tulsa, Oklahoma 74104.

25. Defendant Hoag Cancer Center is believed to be a corporation and citizen of the State of California with an address at One Hoag Drive, Building 41, Newport Beach, California 92658.

26. Defendant Cancer & Hematology Center is believed to be a corporation and citizen of the State of Missouri with an address of Whiteside Medical Building, 2115 S. Freemont Street, Suite 300, Springfield, Missouri 65804.

27. Defendant Patrick Gomez, M.D., the principal investigator at the Cancer & Hematology Center, is a citizen of the United States and the State of Missouri.

28. Defendant Immunex Corporation ("Immunex") is a corporation believed to be a citizen of the State of Washington with an address of 51 University Street, Seattle, Washington 98101.

JURISDICTION

29. This action is a civil action in which this Court has original jurisdiction pursuant to 28 U.S.C. §1331, in that certain counts raise federal questions under 42 U.S.C. §1983 and 45 C.F.R. Part 46.

30. This Court has jurisdiction over the balance of the counts by way of pendant jurisdiction.

31. Venue is appropriate because the claims arose in the Northern District of Oklahoma.

FACTUAL ALLEGATIONS COMMON TO ALL PLAINTIFFS

The Protocol

32. On December 30, 1996, Dr. McGee submitted to the Food and Drug Administration ("FDA") an Investigational New Drug application ("IND") proposing to conduct a human clinical trial at OUHSC-T.

33. Dr. McGee named the drug "Melanoma Vaccine," which was renamed "Allogenic Melanoma Cell Line (IIB-MEL-J), University of Oklahoma Vaccine" ("the Vaccine"). The FDA assigned the application the control designation "BB-IND 6992."

34. The IND was deficient and misleading because, among other things, it referenced preclinical animal studies for a vaccine other than the one which was the subject of the IND and failed to state that no preclinical animal studies supported the injection of the subject Vaccine into humans.

35. At or about this same time, Dr. McGee submitted to the Tulsa IRB protocol number 96-0080-7, proposing to conduct a human clinical trial of the Vaccine ("the Trial") at OUHSC-T involving no more than 15 subjects.

36. The Tulsa IRB approved the protocol on January 8, 1997, and permitted Dr. McGee to begin enrolling patients shortly thereafter and well before the FDA approved the IND on March 11, 1997.

37. As set forth in the protocol submitted to the FDA, the purpose of the Trial was to conduct a controlled clinical trial in a regulated environment to determine the toxicity of the Vaccine. Thereafter, Dr. McGee revised the protocol for a phase I/II study to determine safety/efficacy of the Vaccine and received approval to enroll 25 patients for this phase of the Trial.

38. Over the course of the Trial, certain other entities joined with Dr. McGee to cosponsor the Trial. These were defendants St. John Medical Center, Immunex Corporation, and the Hoag Cancer Center ("the Sponsor Defendants").

39. Throughout the course of the Trial, with the approval and knowledge of the Tulsa IRB, and the Sponsor Defendants, Dr. McGee instead considered it "his goal" to treat patients with a product he considered to be a cure for cancer. That "goal" was in complete disregard of the applicable federal rules and regulations, the protocol approved by the FDA and the Tulsa IRB, and international standards governing the conduct of human clinical trials.

40. Upon obtaining approval to begin the Trial, Dr. McGee sought to obtain patients with varying degrees of melanoma. To that end, Dr. McGee and defendant St. John Medical Center began advertising the Trial, including buying time for a commercial designed to look like a newscast in which the Vaccine was represented to be a cure for cancer. Ultimately, more than 90 patients were admitted to the Trial, more than three times the number in the FDA approved protocol.

The Vaccine

41. The Vaccine was a biological agent prepared by Dr. McGee and his staff using human cancer cells. At a later point, defendant Hoag Cancer Center participated in the process of manufacturing the Vaccine. The Vaccine failed to meet the following standards for the production of such drugs.

a. Cell lines used for preparing the Vaccine were stored with other research cell lines in liquid nitrogen which raised the possibility of exposure to adventitious agents.

b. Because of the absence of defined cell banks, adventitious agent testing described for the cell banks in the IND submission lacked validity, which raised the possibility that the Vaccine was prepared from potentially infected cell lines.

c. No efforts were made to monitor for or maintain the documented heterogeneity of the melanoma cell line. Because no defined cell bank was established for preparation of the Vaccine and because the cell culture conditions for preparation of the Vaccine varied from lot to lot, there was no assurance of consistency in the Vaccine from lot to lot.

d. No logs were maintained for the cell lines used to manufacture the Vaccine to document passage history or conditions of propagation.

e. No formally established standard operating procedures to direct the manufacturing or testing of the Vaccine existed.

f. With respect to the first and second clinical lots, cell culture medial components and the formulation buffer for the Vaccine were changed between the referenced lots; no assessment was done on the potential impact of these changes on product quality or safety.

g. Regarding the manufacture of lot 98MEL1, cell pellets were pooled from cells grown in serum containing and serum free media without an assessment on the impact of these changes on cell culture conditions on product quality.

h. There was no formal or documented characterization of the cell lines used to manufacture the Vaccine.

i. Sterility testing was only performed on one or two vials from a batch size that ranged from 300 to approximately 1000 vials.

j. Testing for endotoxins, mycoplasma and adventitious agents suffered from the same lack of statistically significant sampling as the Sterility testing to detect potential contamination.

k. 98MEL1 batch b was released and injected into patients prior to the appropriate testing for safety and quality.

l. Western Blot testing for identity performed on 98MEL1 batch b revealed the presence of a new band. The lot was released for patient use without determining the impact of the presence of the new band on product quality or safety. In addition, the same band of unknown origin was present in 99MEL1 batches b and c.

m. 99 MEL1 batch b and c were released without appropriate testing for adventitious virus, endotoxin, and general safety.

n. There was no quality assurance/quality control review of the batch records or test results for any of the clinical lots prior to release for patient use.

o. No formally established quality assurance unit was in place.

p. Stability data did not support the five-year expiration period assigned to the Vaccine.

q. No cleaning validation or test data was in place to support the effectiveness of the cleaning procedures used on equipment, glassware, or areas where the Vaccine was manufactured.

r. The dry heat oven used to sterilize and depyrogenate manufacturing and test equipment was not validated.

s. No study existed to demonstrate the container closure integrity for the cryovials in which the Vaccine was dispensed and stored.

t. No formal study existed to determine the Endotoxin Inhibition/Enhancement properties of the Vaccine for 97MEL1, 98MEL1 (all batches), and 99MEL1 (all batches).

u. The individuals involved in the manufacturing of the Vaccine lacked appropriate training, such as "current Good Manufacturing Practices" ("cGMP") training. In addition, there was not an adequate number of personnel to perform the required manufacturing and testing operations.

v. The area(s) where the manufacturing and testing operations took place were not of adequate size and did not facilitate cleaning, maintenance and proper operations. In addition there were no designated areas to perform various manufacturing and testing operations. There were no separate areas designed to prevent mix-ups between quarantined and approved components and finished products.

w. There was a lack of accountability for the finished Vaccine; the number of vials manufactured for a particular lot was unclear or unknown; the current inventory

numbers for finished vials for the various lots was unknown; the calculations of yields did not exist.

x. No established procedures were in place to direct the following operations:

(1) receipt and testing of components;

(2) cleaning operations;

(3) environmental monitoring;

(4) storage of vaccine;

(5) shipping of vaccine.

IMMUNEX CORPORATION

42. On or about February 5, 1999, defendant Immunex agreed to cosponsor the Trial and to provide a biochemical drug to be used in the Trial in combination with the Vaccine known as sargramostim, a recombinant human granulocyte macrophage-colony stimulating factor ("GM-CSF"), which causes certain cells to multiply. In exchange, Immunex received a right of first negotiation to obtain a worldwide license to any patentable drug or protocol arising out of the Trial.

43. Immunex represented that the GM-CSF it was providing would be in "appropriately marked containers. . . . [and] that no dosage form being part of any shipment by Immunex to the Investigator . . . shall be adulterated or misbranded."

44. Immunex agreed that it would provide GM-CFS to the Trial only if Dr. McGee and others associated with administering the Vaccine would adhere to the following:

a. Investigator shall submit the Protocol and any subsequent amendments thereto to Immunex for its approval prior to commencing the Study or implementing amendments, if any.

b. Investigator shall conduct the Study in accordance with the Protocol and the applicable requirements of 21 CFR.

c. Investigator shall obtain the informed consent of each subject/patient participating in the Study in accordance with 21 CFR Part 50. Investigator shall obtain Institutional Review Board review and approval of the Protocol in accordance with 21 CFR Part 56.

d. The Principal Investigator, Dr. Michael McGee, shall disclose, and shall use his reasonable efforts to cause any sub-investigators for the Study to disclose, any information reasonably requested by Immunex to ensure compliance with the requirements of 21 Code of Federal Regulations Part 54, which is summarized in Appendix 2 attached hereto. Such disclosure shall be made in the form and manner reasonably requested by Immunex and promptly upon Immunex's request, and may include, but will not necessarily be limited to, information related to financial interests that the Principal Investigator or sub-investigators hold in Immunex or compensation received by the Principal Investigator or sub-investigators from Immunex for activities other than conducting the Study.

e. It is the Investigator's responsibility to report adverse events promptly under the terms of the Protocol.

f. Investigator shall provide Immunex with a summary of the results of the Study prior to release, directly or indirectly, to any third party.

g. Investigator shall have the sole responsibility for the scientific and technical conduct of the Study.

45. The bottles containing the GM-CSF drugs were labeled, "This is an experimental drug." The top of the box containing the vials stated, "Investigational New Drug."

46. Immunex knew or should have known that Dr. McGee never adhered to the requirements set forth above and that no studies of any kind supported the combination of GM-CSF and the Vaccine in humans, yet Immunex continued to supply the drug and cosponsor the Trial.

The Tulsa IRB

47. An IRB is an institutional review board of at least five members which is charged with the responsibility to be knowledgeable in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

48. Federal regulations mandate that any institution engaged in research, such as OUHSC-T, must have an IRB to ensure that human clinical trials are designed and conducted in accordance with sound scientific and ethical principals.

49. An IRB has the responsibility to review and approve all aspects of a human clinical trial including the design of the protocol, the qualifications of the investigator, the informed consent document, the selection process of participants, the balance of risks and benefits, and the conduct of the trial.

50. The Tulsa IRB was comprised of the IRB Defendants; included among them was defendant Dr. Donovan who, as the Chief Bioethicist at OUHSC-T, assumed the responsibility of ensuring that this and other clinical trials at OUHSC-T comported with generally accepted ethical standards.

51. The IRB Defendants, in general, and Dr. Donovan, in particular, did not properly perform their functions in that they failed to examine the design of the protocol, examine the qualifications of Dr. McGee, review the operation of the Trial, assure the protection of the participants, review proposed amendments to the informed consent forms provided to patients, review amendments to the protocol, approve advertisements for the Trial, ensure proper reporting, and make certain that the Trial comported with ethical standards.

52. Specific failures included:

a. Nonadherence to 45 CFR 46.115(2) in that Tulsa IRB meeting minutes repeatedly lacked detail to document discussion of issues and/or adequate basis for requiring changes in protocols and/or informed consent documents.

b. No documentation reflecting that the Tulsa IRB reviewed or considered investigator brochures, case report forms or subject recruitment information related to studies under consideration. The document common practice was to review only the protocol and informed consent information.

c. Excessive use of administrative (expedited) review by the Tulsa IRB chairman.

d. Common practice included a pre-review of documentation by the sponsored programs administrator, recommendation for approval, followed by administrative approval by the chairman. The full board was then informed at subsequent meetings. Documentation regularly included unanimous approval and lacked documentation of discussion of these administrative actions.

e. Annual review and approval of on-going research was accomplished through administrative review.

f. Tulsa IRB records did not include final protocols, particularly when changes had been requested. According to documentation, required changes were not reviewed by the full board, but received administrative review and approval, with notification only of the full board at a subsequent meeting.

g. The Tulsa IRB had no reporting responsibility to the OUHSC-Oklahoma City IRB organization.

h. Documentation present in the Trial files regarding the conduct of an FDA inspection of the Tulsa IRB in 1998 revealed FDA form 483 observations similar in nature to those set forth above.

i. The Tulsa IRB could not provide historical membership lists older than two years.

53. The Tulsa IRB's conduct with respect to the Trial was not an isolated event but instead reflected its ordinary course of business.

54. There was a significant lack of understanding in the Tulsa IRB both of 45 CFR Part 46 and 21 CFR, including the cGMP and cGCP requirements.

55. In addition, there appeared to be excessive use of administrative review and other time-saving mechanisms. The average Tulsa IRB meeting appeared to take one hour and included dinner to follow. Given the number of active protocols, safety reports, and other matters processed by the chair, no deliberative review could have occurred during this time.

Informed Consent Forms

56. All patients selected to participate in the Trial were provided an "Individual's Consent to Voluntary Participation in a Research Project" form ("consent form").

57. Plaintiffs Dawanna Robertson, Jeffrey Teel, Don Horn, Deborah Butler, Dorothy Wynn, Mark Gaffney, Beverly Ann Harris, Ella Watkins, Kathleen C. Weddle and James F. Freisner ("Plaintiff Participants") each were given the consent form and other documents, which purportedly were to provide certain information necessary to make an informed decision as to whether they were going to take part in and were appropriate candidates for the Trial.

58. These consent forms, other documents and discussions were materially misleading and deceptive because, among other things:

a. The consent form falsely implied that the FDA approved the Trial of the Vaccine and GM-CSF and their experimental use when the Trial that was actually implemented was different than the proposed Trial submitted for approval to the FDA.

b. The consent form falsely stated that "[t]he medical and scientific basis for the use of such a vaccine comes from studies in both animals and humans showing that, from these cells, factors are obtained that appear to assist the body to reject cancer." In actuality, no proper studies were conducted on either animals or humans.

c. The consent form falsely stated that risks subjects could expect included only local skin reddening; itching, swelling, and pain; and occasional temporary fever. In addition, the consent form provided that "fever, weakness, headache, bone and muscle pain, and chills have occurred with GM-CSF and can be prevented or reduced with Tylenol or Advil. Additional side effects may include swelling in the feet and hands due to water retention, difficulty breathing and rash." In fact, Plaintiff Participants suffered through much more dangerous and painful side effects.

d. The consent form stated that "records of the Trial would be kept confidential and that the subject would not be identifiable by name or description in any reports or publications. In actuality, the records of the Trial were not kept confidential and the subjects were identified by name in reports.

e. Dr. McGee, the principal investigator, failed to adequately discuss the consent form with the plaintiffs, failed to advise them of the true nature of the Trial, and instead advised them that he had the cure for their cancer.

f. Certain versions of the consent form indicated that pregnant women were prohibited from participating in the Trial and that participants in the Trial should not become pregnant or impregnate women while in the Trial, while other drafts of the consent form did not contain this provision.

59. As a result of these and other deficiencies and misrepresentations, Plaintiff Participants were led to believe the risks of the Trial were minimal and the potential benefits of their participation to present treatment for themselves and the future treatment of melanoma were enormous.

60. The effects of such misrepresentations and nondisclosures were that Plaintiff Participants agreed to participate and continue in the Trial.

The Conduct of the Trial

61. Cherlynn Mathias, Nurse Coordinator at OUHSC-T Surgery Department began her employment on June 1, 1999.

62. She was hired as a Nurse Coordinator assigned to the Allogenic Melanoma Cell Line and thereafter was assigned to work on the Trial.

63. Nurse Mathias discovered numerous procedural and substantive problems with the way the Trial was conducted.

64. Nurse Mathias noted faulty or non-existent quality control and assurance procedures with respect to the manufacture, storage and shipping of the Vaccine, inadequate patient

examinations before and after injections, serious inattention to the reporting of adverse events related to the use of the Vaccine, over enrollment of subjects in the Trial, and the admission of subjects in the Trial who were not eligible under the FDA approved protocol because of the severity of their illness or pregnancy.

65. Nurse Mathias repeatedly advised defendants McGee, Plunket, Wortham, Brooks, Broughan and Donovan of the unlawful and unsafe practices in the Trial and the need to report the errant practices to the federal regulators; yet no action was taken.

66. Dr. McGee told Nurse Mathias that God guided him on a path to cure cancer and that his only concern was to give the Vaccine as a treatment for melanoma patients.

67. As a result of the continued non-action, Nurse Mathias presented a formal overview of the compliance infractions to Dr. Broughan, Head of the Department of Surgery on December 13th and again to Dr. McGee and Dr. Wortham, Director of the Office of Research on December 14th 1999.

68. Nurse Mathias recommended that OUHSC-T hire a Contract Research Organization ("CRO") for an outside audit, implement a plan to monitor remote sites, file FDA form 1572's on the Investigators, make the lab compliant with FDA regulations, and stop enrolling new patients.

69. In January 2000, OUHSC-T brought in a CRO named RayCar and Associates to conduct a one-day audit after which, if hired, it would conduct a full audit. At the conclusion of this initial review, the auditor advised Dr. Broughan, Dr. Wortham, Dr. Plunket, and Dr. McGee that serious violations of the law had occurred, that serious risks to patient safety existed, and that the FDA should be notified of the infractions.

70. Dr. McGee then telephoned safety officer Karen Jones of the FDA, but instead of advising Ms. Jones of the safety violations in the Trial, Dr. McGee represented that any lack of compliance was due to faulty paperwork.

71. OUHSC-T then hired another CRO firm, Hausmann and Wynne Associates, Inc. ("Hausmann and Wynne"), to conduct a full audit in or about the first week in March 2000.

72. On or about March 16, 2000, Hausmann and Wynne issued a report to defendants Dr. McGee and Dr. Broughan that serious safety and other violations had occurred and that the Trial should immediately terminate; it was thereafter decided that these findings would be distributed only on "a need to know basis," meaning not to the FDA or the patients.

73. By letter dated April 3, 2000, Dr. McGee with the knowledge and approval of others at OUHSC-T, represented to the patients in the Trial that it was closing due to an inadequate supply of the Vaccine; this was false and a deliberate misrepresentation. Neither the patients nor the FDA were advised of the safety violations.

FDA Involvement

74. Because of the failure of OUHSC-T to inform the patients and the FDA of the serious safety infractions, Nurse Mathias contacted the Division of Human Subject Projections, Office of Protection from Research Risks, National Institute of Health (known since June 18, 2000 as the Office of Human Research Protections in the Office of the Secretary or "OHRP").

75. On June 12, 2000, Dr. Michael Carome of the OHRP faxed a letter to the University of Oklahoma indicating he had received allegations of non-compliance with the Department of Health and Human Services Regulation for the Protection of Human Research Subjects.

76. Upon receipt of the letter from the OHRP and at the demand of the University of Oklahoma, OUHSC-T ordered another audit by a CRO named Quintiles Transactional Corp..

77. By letter dated June 29, 2000, the OHRP advised OUHSC-T that it had found serious violations with respect to the Trial and to the Tulsa IRB's review and supervision of the Trial.

78. On June 30, 2000, OUHSC-T provided a report of the Quintiles audit, prepared in response to Dr. Carome's June 12, 2000 letter.

79. The audit was highly critical of the Trial, finding, among other things:

> a. All of the research conducted by Dr. McGee under the BB-IND 6692 seems to have been conducted with vaccine produced from a cell line provided by a Dr. Medrano at Baylor. The word "seems" is used in this case, since related documentation may imply the use of other cell lines as well. There is simply insufficient clarity to make a finding with certainty. It is clear, however, that the manufacturing process, like the clinical approach, also evolved with time and experience. Insufficient supplies associated with both manufacturing difficulties and with attempts to include increased numbers of patients, seem to have triggered concerns about the quality of the vaccine being used and the suitability of its use for human subjects. Minimally, it is clear from the documentation examined that the manufacture, testing and distribution of the vaccine was not in compliance with FDA regulation, guidance or expectations.
>
> b. The inclusion of patients self administering the vaccine, as well as GM-CSF (off label) seems to have placed at risk a vulnerable population, in that no evidence was observed that proper temperature and/or quality controls were provided for vaccine sent to patients or other institutions. It is likewise apparent from letters sent April 19, 2000 (St. Johns) and May 16, 2000 (Vanderbilt) that patients were treated in remote sites without local IRB review and approval of the McGee protocol. This is particularly problematic, in that the local IRB ought reasonably to be seen as the local patient advocate, but was unaware of the circumstances of the trials. Finally, although it may simply have not been noted in the 13 volumes of paper reviewed by Dr. Hensley, on the 27th, no evidence of FDA approval of the new protocol was seen.

> c. The word "treat" is used in the above findings to underscore a primary finding in this matter, in that it is apparent that Dr. McGee was conducting what would in decades past be described as "therapeutic research," in that his objective appears to have been to treat patients with a potentially promising new product, rather than to conduct controlled clinical trials in a regulated environment. An apparently close relationship with IRB Chair, Dr. Plunket, together with Dr. Plunket's apparent propensity to provide administrative approval of amendments and other matters, seems to have encouraged this method of operation. Certainly Dr. McGee was in no manner inhibited by the IRB in his course of action.

80. The audit also found there was "an intent to deceive at the very time that full disclosure is most needed."

81. In or about July 2000, Dr. Wortham was removed from his position as Director of the Tulsa Office of Research, Dr. Plunket was removed from his position as Chair of the Tulsa IRB, and Dr. McGee was removed as Assistant Chair of Surgery and Research Professor, relieved all administrative functions.

82. By letter dated July 20, 2000, the University of Oklahoma terminated Dr. Brooks, Dean of the College of Medicine-Tulsa, citing "professional incompetence or dishonesty [and] substantial, manifest, or repeated failure to fulfill professional duties and responsibilities or to adhere to University policies" due to their "knowledge of multiple serious problems" with the Trial, including:

> noncompliance with the Department of Health and Human Services regulations for protection of human subjects and the requirements of the IRB and noncompliance with Federal Drug Administration regulations, and, as Dean of the College of Medicine-Tulsa, participated in decisions not to inform adequately the patients who participated in the trial, the Office for Protection of Research Risks (now Office for Human Research Protections), the Federal Drug Administration, the University of Oklahoma-Tulsa Institutional Review Board, the Senior Vice President and Provost of the

University of Oklahoma Health Sciences Center, the Vice Senator for Research, the Associate Vice Senator for Clinical Trials, or any person within the University of Oklahoma who might have been able to advise you on proper corrective actions.

83. Dr. Brooks and Dr. Wortham later filed suit to contest their termination claiming its purpose was "to cover up the lack of research compliance procedures ..." at OUHSC-T.

84. From July 17 through August 4, 2000, the Department of Health and Human Services, Public Health Service of the FDA audited the Trial.

85. On August 4, 2000, the FDA, through investigators Joel Martinez and David M. Beltran, issued a four page report detailing its findings of numerous infractions and safety violations, including:

a. Inclusion of patients which did not meet the Study protocol criteria.
b. Failure to perform all Trial protocol procedures as required. For example:
    1. Pregnancy tests as appropriate;
    2. Screening for HIV and HbsAg;
    3. Performance of physical exams;
    4. Use of multiple observers to reduce investigator bias in the evaluation of any questionable side effects and/or tumor changes;
    5. Evaluation of DTH responses by two individuals;
    6. Vaccine injection treatment schedule;
    7. Performance of Western Blot analysis to ascertain hormonal immune response;
    8. Require patients to remain in the physician's office for 30 minutes;
    9. Skin test for DTH at Weeks 8, 20, 32, 44, 68 and 92;
    10. Performance of CTL assays;
    11. Laboratory analyses;
    12. Chest X-rays/CT Scans of the Chest/Abdomen/Pelvis;
c. Patients were not discontinued from treatment after evidence of disease progression was noted;
d. patients were allowed to continue in the Trial after adjuvant therapy was given;

e. abnormal lab results were not reviewed to determine clinical significance;
f. use of Trial related advertisement without IRB approval;
g. failure to accurately notify the IRB of patient enrollment. For example, a correspondence dated 8-1-97 states 15 patients have been enrolled as requested under BB-IND 6992. A patient log dated 7-5-00 shows the enrollment of 21 patients as of 8-1-97.

86. The report also concluded that OUHSC-T, as the sponsor of the Trial, committed the following infractions:

a. failure to exercise proper control of an investigational drug as shipments were made directly to patients;
b. failure to obtain signed FDA 1572's for investigators participating in the Vaccine Trial and prior to shipment of the Vaccine;
c. failure to assure IRB approval is in place for those investigators participating in the Melanoma trial and prior to shipment of the Vaccine;
d. failure to properly monitor those investigators participating in the Trial to assure compliance with the Trial protocol, control of the Vaccine, and protection of human subjects;
e. failure to submit IND annual reports as required;
f. failure to keep accurate records with respect to the final disposition of the Vaccine;
g. failure to report protocol revisions/amendments;
h. failure to report/include all dropouts, adverse events, and deaths as a part of the IND annual reports;
i. failure to establish written procedures for monitoring clinical sites to assure compliance with requirements of the Trial protocol;
j. no documentation to show pre-Trial and Trial monitoring visits were accomplished at all investigator sites; and
k. failure to report serious adverse events occurring at other clinical sites.

87. The report also concluded the Tulsa IRB had, among other things:

a. failed to assure proper protection of human subjects as the IRB approved instructions for self administration of Vaccine by patients outside the supervision of an investigator participating in the Trial;

b. approved of major amendments/changes to the Trial protocol via expedited review;
c. not presented Trial related protocol waivers to the full Board for approval prior to enrollment of the patient; and
d. failed to require approval of Trial related advertisements prior to use by the clinical investigator.

88. Additional infractions included, but were not limited to, deviating from the protocol, missing documentation, shipping of drugs to people's homes, allowing subjects to self-inject, missing data in the case report forms, failing to report adverse events, enrolling ineligible patients, and allowing patients to receive other treatments while enrolled in the Trial.

89. These infractions and safety violations render the Trial void of any research, scientific or medical value.

FIRST CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

90. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

91. Dawanna Robertson suffered from melanoma and was advised of the opportunity to participate in the Trial through one of her caretakers.

92. On or about January 26, 1999, Dawanna Robertson met with Dr. McGee to discuss her participation in the Trial and the informed consent document.

93. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Ms. Robertson to participate; this was prior to any approval by the Tulsa IRB of the informed consent document.

94. As a result of being injected with the Vaccine and the GM-CSF, Dawanna Robertson suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression.

95. Sometime during the course of her treatment with the Vaccine, Dawanna Robertson learned she was pregnant and, shortly thereafter, advised Dr. McGee that she was pregnant and asked whether she could remain in the Trial.

96. Dr. McGee advised her that she could remain an active participant in the Trial as the risks were minimal and did not advise her the FDA approved protocol expressly excluded any pregnant participant.

97. Dawanna Robertson's daughter, Sydnee Robertson, was born on January 30, 2000.

98. The Nuremberg Code and the Declaration of Helsinki are the minimum international standards of conduct governing biomedical research on human subjects; they are in essence world statutes to which the citizens of all nations are subject.

99. The Nuremberg Code, drafted in response to the horrors of Nazi experimentation on human subjects, set forth basic principals "to satisfy moral ethical and legal concepts."

100. The Nuremberg Code provides in pertinent part:

> The voluntary consent of the human subject is absolutely essential. . . . . before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> . . .
>
> The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease

> or other problem understudy that the anticipated results will justify the performance of the experiment.
>
> . . .
>
> The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
>
> . . .
>
> Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
>
> . . .
>
> The experiment should be conducted only by scientifically qualified persons.

101. The World Health Organization established the Declaration of Helsinki to further the goals of the Nuremberg Code and to set the minimum acceptable standards in all nations in which human clinical trials are conducted. These include:

> Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
>
> . . .
>
> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
>
> . . .
>
> Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person..
>
> . . .
>
> Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objectives is in proportion to the inherent risk to the subject.
>
> . . .
>
> Concern for the interests of the subject must always prevail over the interest of science and society.
>
> . . .

> The right of the research subject to safeguard his or her integrity must always be respected.
>
> . . .
>
> Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazzards involved are believed to be predictable.
>
> . . .
>
> In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.

102. The common law has recognized such standards as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial.

103. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

104. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SECOND CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

105. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

106. 21 CFR §210, 211 and 21 CFR §601, 610, part of the code of Federal Regulations, establish the law of the United States with respect to the manufacture and control of investigational biological drugs for clinical use.

107. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

108. These latter regulations require:

> Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subject to risk.
>
> . . .
>
> Risks to subjects are reasonable in relation to anticipated benefits . . .
>
> . . .
>
> Selection of subjects is equitable.
>
> . . .
>
> Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
>
> . . .
>
> Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
>
> . . .
>
> Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.
>
> . . .
>
> Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
>
> . . .
>
> Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

109. These regulations also require institutions such as OUHSC-T to appoint an IRB to review the design of any clinical trial protocol and to ensure that the conduct of any clinical trial at the institution is consistent with the requirements of the regulations.

110. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRD CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

111. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

112. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

113. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of her constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to her great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Dawanna Robertson demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FOURTH CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

114. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

115. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

116. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

117. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

118. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

119. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Dawanna Robertson demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTH CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

120. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

121. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

122. The conduct of defendants in making false statements to plaintiff knowing she would rely on these statements in determining whether she should participate in the Trial has caused emotional harm and was extreme and outrageous.

123. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTH CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

124. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

125. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

126. The misrepresentations set forth above were done with the knowledge that they were false when made.

127. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

128. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to her detriment.

WHEREFORE, for the above-stated reasons, plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTH CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

129. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

130. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining her in order to determine her condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which she remained under said defendants' care and treatment.

131. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

132. In addition, Treating Defendants allowed the plaintiff to continue in the Trial despite the knowledge that she was pregnant, thereby putting her baby, Sydnee Robertson, at risk.

133. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the plaintiff of all the risks of performing the Trial so as to afford her with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

134. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to her loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

135. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

136. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

137. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to her loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

WHEREFORE, for the above-stated reasons, plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTH CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

138. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

139. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon her so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINTH CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

140. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

141. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

142. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

143. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TENTH CAUSE OF ACTION

PLAINTIFF DAWANNA ROBERTSON VS. ALL DEFENDANTS

PUNITIVE DAMAGES

144. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

145. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Dawanna Robertson demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ELEVENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

146. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

147. Jeffrey Teel suffered from melanoma and was advised of the opportunity to participate in the Trial through one of his caretakers.

148. On or about June 6, 1998, Jeffrey Teel met with Dr. McGee to discuss his participation in the Trial and the informed consent document.

149. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Mr. Teel to participate.

150. As a result of being injected with the Vaccine, Jeffrey Teel suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea, fever, diarrhea, anxiety and depression.

151. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

152. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWELVETH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

153. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

154. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

155. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTEENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

156. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

157. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

158. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of his constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to his great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Jeffrey Teel demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FOURTEENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

159. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

160. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

161. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

162. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

163. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

164. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Jeffrey Teel demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTEENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

165. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

166. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

167. The conduct of defendants in making false statements to plaintiff knowing he would rely on these statements in determining whether he should participate in the Trial has caused emotional harm and was extreme and outrageous.

168. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTEENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

169. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

170. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

171. The misrepresentations set forth above were done with the knowledge that they were false when made.

172. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

173. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to his detriment.

WHEREFORE, for the above-stated reasons, plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTEENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

174. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

175. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining him in order to determine his condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

176. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

177. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the plaintiff of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

178. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

179. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

180. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

181. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

WHEREFORE, for the above-stated reasons, plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTEENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

182. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

183. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon him so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETEENTH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

184. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

185. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

186. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the patients:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

187. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTIETH CAUSE OF ACTION

PLAINTIFF JEFFREY TEEL VS. ALL DEFENDANTS

PUNITIVE DAMAGES

188. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

189. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Jeffrey Teel demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-FIRST CAUSE OF ACTION

PLAINTIFF DON HORN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

190. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

191. Don Horn suffered from melanoma and was advised of the opportunity to participate in the Trial through one of his caretakers.

192. On or about December 1, 1999, Don Horn met with Dr. McGee to discuss his participation in the Trial and the informed consent document; Don Horn was not eligible to participate under the protocol approved by the FDA because of the severity of his illness.

193. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Mr. Horn to participate.

194. As a result of being injected with the Vaccine and the GM-CSF, Don Horn suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression; Don Horn died on January 17, 2000, six weeks after enrolling in the Trial; his death was not reported as an adverse event to anyone.

195. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

196. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-SECOND CAUSE OF ACTION

PLAINTIFF DON HORN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

197. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

198. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

199. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-THIRD CAUSE OF ACTION

PLAINTIFF DON HORN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

200. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

201. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

202. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of his constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to his great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Don Horn demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-FOURTH CAUSE OF ACTION

PLAINTIFF DON HORN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

203. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

204. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

205. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

206. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

207. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

208. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Don Horn demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-FIFTH CAUSE OF ACTION

PLAINTIFF DON HORN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

209. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

210. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

211. The conduct of defendants in making false statements to plaintiff knowing he would rely on these statements in determining whether he should participate in the Trial has caused emotional harm and was extreme and outrageous.

212. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-SIXTH CAUSE OF ACTION

PLAINTIFF DON HORN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

213. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

214. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

215. The misrepresentations set forth above were done with the knowledge that they were false when made.

216. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

217. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to his detriment.

WHEREFORE, for the above-stated reasons, plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-SEVENTH CAUSE OF ACTION

PLAINTIFF DON HORN VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

218. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

219. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining him in order to determine his condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

220. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

221. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the patient of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

222. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

223. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

224. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

225. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to his, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

WHEREFORE, for the above-stated reasons, plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-EIGHTH CAUSE OF ACTION

PLAINTIFF DON HORN VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

226. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

227. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon him so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

TWENTY-NINTH CAUSE OF ACTION

PLAINTIFF DON HORN VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

228. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

229. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

230. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

231. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTIETH CAUSE OF ACTION

PLAINTIFF DON HORN VS. ALL DEFENDANTS

PUNITIVE DAMAGES

232. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

233. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, Plaintiff Don Horn demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-FIRST CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

234. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

235. Deborah Butler suffered from melanoma and was advised of the opportunity to participate in the Trial through one of her caretakers.

236. On or about August 17, 1999, Deborah Butler met with Dr. McGee to discuss her participation in the Trial and the informed consent document.

237. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Ms. Butler to participate.

238. As a result of being injected with the Vaccine and the GM-CSF, Deborah Butler suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression.

239. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

240. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-SECOND CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

241. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

242. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

243. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-THIRD CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

244. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

245. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

246. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of her constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to her great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Deborah Butler demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-FOURTH CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

247. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

248. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

249. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

250. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

251. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

252. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Deborah Butler demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-FIFTH CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

253. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

254. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

255. The conduct of defendants in making false statements to plaintiff knowing she would rely on these statements in determining whether she should participate in the Trial has caused emotional harm and was extreme and outrageous.

256. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-SIXTH CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

257. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

258. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

259. The misrepresentations set forth above were done with the knowledge that the misrepresentations were false when made.

260. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

261. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to her detriment.

WHEREFORE, for the above-stated reasons, plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-SEVENTH CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

262. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

263. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining her in order to determine her condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which she remained under said defendants' care and treatment.

264. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

265. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the plaintiff of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

266. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

267. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

268. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

269. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

WHEREFORE, for the above-stated reasons, plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-EIGHTH CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

270. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

271. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon her so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

THIRTY-NINTH CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

272. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

273. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

274. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

275. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTIETH CAUSE OF ACTION

PLAINTIFF DEBORAH BUTLER VS. ALL DEFENDANTS

PUNITIVE DAMAGES

276. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

277. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Deborah Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-FIRST CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

278. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

279. Dorothy Wynn suffered from melanoma and was advised of the opportunity to participate in the Trial through one of her caretakers.

280. On or about August 5, 1999, Dorothy Wynn met with Dr. McGee to discuss her participation in the Trial and the informed consent document.

281. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Ms. Wynn to participate.

282. As a result of being injected with the Vaccine and the GM-CSF, Dorothy Wynn suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression.

283. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

284. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Dorothy Wynn demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-SECOND CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

285. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

286. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

287. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Dorothy Wynn demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-THIRD CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

288. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

289. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

290. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of her constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to her great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Dorothy Wynn demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-FOURTH CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

291. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

292. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

293. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

294. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

295. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

296. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Dorothy Wynn demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-FIFTH CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

297. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

298. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

299. The conduct of defendants in making false statements to plaintiff knowing she would rely on these statements in determining whether she should participate in the Trial has caused emotional harm and was extreme and outrageous.

300. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Dorothy Wynn demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-SIXTH CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

301. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

302. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

303. The misrepresentations set forth above were done with the knowledge that they were false when made.

304. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

305. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to her detriment.

WHEREFORE, for the above-stated reasons, plaintiff Dorothy Wynn demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-SEVENTH CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

306. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

307. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining her in order to determine her condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which she remained under said defendants' care and treatment.

308. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

309. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the patient of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

310. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

311. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

312. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

313. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

WHEREFORE, for the above-stated reasons, plaintiff Dorothy Butler demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-EIGHTH CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

314. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

315. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon her so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Dorothy Wynn demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FORTY-NINTH CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

316. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

317. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

318. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

319. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Dorothy Wynn demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTIETH CAUSE OF ACTION

PLAINTIFF DOROTHY WYNN VS. ALL DEFENDANTS

PUNITIVE DAMAGES

320. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

321. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Dorothy Wynn demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit

FIFTY-FIRST CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

322. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

323. Mark Gaffney suffered from melanoma and was advised of the opportunity to participate in the Trial through one of his caretakers.

324. On or about May 18, 1999, Mark Gaffney met with Dr. McGee to discuss his participation in the Trial and the informed consent document.

325. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Mr. Gaffney to participate.

326. As a result of being injected with the Vaccine and the GM-CSF, Mark Gaffney suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression.

327. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

328. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-SECOND CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

329. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

330. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

WHEREFORE, for the above-stated reasons, plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-THIRD CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

331. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

332. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

333. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of his constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to his great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Mark Gaffney demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-FOURTH CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

334. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

335. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

336. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

337. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

338. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

339. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Mark Gaffney demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-FIFTH CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

340. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

341. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

342. The conduct of defendants in making false statements to plaintiff knowing he would rely on these statements in determining whether he should participate in the Trial has caused emotional harm and was extreme and outrageous.

343. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-SIXTH CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

344. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

345. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

346. The misrepresentations set forth above were done with the knowledge that they were false when made.

347. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

348. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to his detriment.

WHEREFORE, for the above-stated reasons, plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-SEVENTH CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

349. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

350. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining him in order to determine his condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

351. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

352. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the patient of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

353. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

354. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

355. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

356. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

WHEREFORE, for the above-stated reasons, plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-EIGHTH CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

357. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

358. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon him so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

FIFTY-NINTH CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

359. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

360. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

361. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

362. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTIETH CAUSE OF ACTION

PLAINTIFF MARK GAFFNEY VS. ALL DEFENDANTS

PUNITIVE DAMAGES

363. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

364. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Mark Gaffney demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-FIRST CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS, SPONSOR DEFENDANTS CANCER & HEMATOLOGY CENTER AND PATRICK GOMEZ, M.D.

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

365. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

366. Beverly Ann Harris suffered from melanoma and was advised of the opportunity to participate in the Trial through one of her caretakers.

367. On or about August 4, 1999, Beverly Ann Harris met with Dr. McGee to discuss her participation in the Trial and the informed consent document.

368. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Ms. Harris to participate.

369. After her initial injection, Beverly Harris received the majority of her injections at Cancer & Hematology Center in Springfield, Missouri, under the care of Dr. Gomez.

370. As a result of being injected with the Vaccine and the GM-CSF, Beverly Ann Harris suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression.

371. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

372. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Beverly Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-SECOND CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS, SPONSOR DEFENDANTS, CANCER & HEMATOLOGY CENTER AND PATRICK GOMEZ, M.D.

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

373. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

374. 45 CFR §46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

375. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Beverly Ann Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-THIRD CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS, SPONSOR DEFENDANTS, CANCER & HEMATOLOGY CENTER AND PATRICK GOMEZ, M.D.

42 U.S.C. §1983/CIVIL RIGHTS

376. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

377. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

378. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of her constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to her great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Beverly Ann Harris demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-FOURTH CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

379. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

380. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

381. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

382. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

383. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

384. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Beverly Ann Harris demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-FIFTH CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS, SPONSOR DEFENDANTS, CANCER & HEMATOLOGY CENTER AND PATRICK GOMEZ, M.D.

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

385. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

386. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

387. The conduct of defendants in making false statements to plaintiff knowing she would rely on these statements in determining whether she should participate in the Trial has caused emotional harm and was extreme and outrageous.

388. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Beverly Ann Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-SIXTH CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS, SPONSOR DEFENDANTS, CANCER & HEMATOLOGY CENTER AND PATRICK GOMEZ, M.D.

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

389. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

390. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

391. The misrepresentations set forth above were done with the knowledge that they were false when made.

392. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

393. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to her detriment.

WHEREFORE, for the above-stated reasons, plaintiff Beverly Ann Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-SEVENTH CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, CANCER & HEMATOLOGY CENTER, PATRICK GOMEZ, M.D., IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

394. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

395. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center, Cancer & Hematology Center and Patrick Gomez, M.D. ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining her in order to determine her condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which she remained under said defendants' care and treatment.

396. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

397. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the patient of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

398. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

399. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

400. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

401. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

WHEREFORE, for the above-stated reasons, plaintiff Beverly Ann Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-EIGHTH CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. DR. MCGEE ST. JOHN MEDICAL CENTER, CANCER & HEMATOLOGY CENTER AND PATRICK GOMEZ, M.D.

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

402. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

403. Defendants, and each of them respectively, failed to inform the plaintiff the risks of all treatment, care, therapy and procedures performed upon her so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Beverly Ann Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SIXTY-NINTH CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

404. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

405. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

406. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

407. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Beverly Ann Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTIETH CAUSE OF ACTION

PLAINTIFF BEVERLY ANN HARRIS VS. ALL DEFENDANTS

PUNITIVE DAMAGES

408. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

409. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Beverly Ann Harris demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-FIRST CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

410. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

411. Ella Watkins suffered from melanoma and was advised of the opportunity to participate in the Trial through one of her caretakers.

412. On or about May 24, 1999, Ella Watkins met with Dr. McGee to discuss her participation in the Trial and the informed consent document; Ella Watkins was not eligible to participate under the protocol approved by the FDA because of her age.

413. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Ms. Watkins to participate.

414. As a result of being injected with the Vaccine and the GM-CSF, Ella Watkins suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression; Ella Watkins died on January 8, 2000, less than seven months after enrolling in the Trial; her death was not reported as an adverse event to anyone.

415. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

416. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-SECOND CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

417. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

418. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

419. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-THIRD CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

420. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

421. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

422. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of her constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to her great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Ella Watkins demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-FOURTH CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

423. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

424. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

425. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

426. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

427. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

428. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Ella Watkins demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-FIFTH CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

429. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

430. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

431. The conduct of defendants in making false statements to plaintiff knowing she would rely on these statements in determining whether she should participate in the Trial has caused emotional harm and was extreme and outrageous.

432. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-SIXTH CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

433. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

434. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

435. The misrepresentations set forth above were done with the knowledge that they were false when made.

436. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

437. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to his detriment.

WHEREFORE, for the above-stated reasons, plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-SEVENTH CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

438. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

439. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining her in order to determine her condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which she remained under said defendants' care and treatment.

440. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

441. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff condition under all of the circumstances;

h. caring for the plaintiff's in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the patient of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

442. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to her loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

443. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

444. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

445. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to her loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

WHEREFORE, for the above-stated reasons, plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-EIGHTH CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

446. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

447. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon her so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

SEVENTY-NINTH CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

448. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

449. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

450. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

451. By conducting themselves as described above, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTIETH CAUSE OF ACTION

PLAINTIFF ELLA WATKINS VS. ALL DEFENDANTS

PUNITIVE DAMAGES

452. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

453. Defendants' actions as described above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Ella Watkins demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-FIRST CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

454. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

455. Shirley Rogers suffered from melanoma and was advised of the opportunity to participate in the Trial through one of her caretakers.

456. On or about _____, 1998, Shirley Rogers met with Dr. McGee to discuss her participation in the Trial and the informed consent document.

457. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Mrs. Rogers to participate.

458. As a result of being injected with the Vaccine, Shirley Rogers suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea, anxiety and depression.

459. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

460. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Shirley Rogers demands judgment in her favor against defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-SECOND CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

461. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

462. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

463. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Shirley Rogers demands judgment in her favor against defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-THIRD CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

464. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

465. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

466. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of his constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to his great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Shirley Rogers demands judgment in his favor against the defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-FOURTH CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

467. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

468. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

469. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

470. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

471. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

472. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Shirley Rogers demands judgment in her favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-FIFTH CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

473. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

474. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

475. The conduct of defendants in making false statements to plaintiff knowing he would rely on these statements in determining whether he should participate in the Trial has caused emotional harm and was extreme and outrageous.

476. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Shirley Rogers demands judgment in his favor against defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-SIXTH CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

477. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

478. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

479. The misrepresentations set forth above were done with the knowledge that they were false when made.

480. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

481. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to his detriment.

WHEREFORE, for the above-stated reasons, plaintiff Shirley Rogers demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-SEVENTH CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

482. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

483. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining him in order to determine his condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and

of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

484. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

485. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the plaintiff of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

486. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would

administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

487. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

488. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

489. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss

and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

WHEREFORE, for the above-stated reasons, plaintiff Shirley Rogers demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-EIGHTH CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

490. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

491. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon him so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Shirley Rogers demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

EIGHTY-NINTH CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

492. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

493. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

494. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the patients:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

495. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Shirley Rogers demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETIETH CAUSE OF ACTION

PLAINTIFF SHIRLEY ROGERS VS. ALL DEFENDANTS

PUNITIVE DAMAGES

496. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

497. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Shirley Rogers demands judgment in her favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-FIRST CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

498. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

499. Kathleen C. Weddle suffered from melanoma and was advised of the opportunity to participate in the Trial through one of her caretakers.

500. On or about the __ day of _____, 1998, Kathleen Weddle met with Dr. McGee to discuss her participation in the Trial and the informed consent document.

501. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Mrs. Weddle to participate.

502. As a result of being injected with the Vaccine, Kathleen C. Weddle suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea, anxiety and depression.

503. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

504. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, Plaintiff, Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle, Deceased demands judgment in his favor against defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-SECOND CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

505. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

506. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

507. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff.

WHEREFORE, for the above-stated reasons, Plaintiff, Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle demands judgment in his favor against defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-THIRD CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

508. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

509. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

510. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of her constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to his great detriment and damage.

WHEREFORE, for the above-stated reasons, Plaintiff, Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle demands judgment in his favor against the defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-FOURTH CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

511. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

512. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

513. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

514. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

515. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

516. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the Plaintiff, Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle, demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-FIFTH CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

517. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

518. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

519. The conduct of defendants in making false statements to plaintiff knowing she would rely on these statements in determining whether he should participate in the Trial has caused emotional harm and was extreme and outrageous.

520. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle demands judgment in his favor against defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-SIXTH CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

521. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

522. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

523. The misrepresentations set forth above were done with the knowledge that they were false when made.

524. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

525. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to her detriment.

WHEREFORE, for the above-stated reasons, Plaintiff Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-SEVENTH CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

526. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

527. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally,

were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining him in order to determine his condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

528. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

529. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the plaintiff of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

530. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff was prevented from performing all of her usual duties, occupations, recreational activities and avocation all to her loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would

administer the cure to her, plaintiff lost time to perform all of her usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

531. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

532. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

533. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of her usual duties, occupations, recreational activities and avocation all to her loss and detriment. In addition, as plaintiff had been led to believe there was a cure for her disease and that defendants would administer the cure to her, plaintiff lost time to perform all of her usual duties,

occupation, recreational activities and avocation and has been prevented from coming to terms with her disease.

WHEREFORE, for the above-stated reasons, Plaintiff Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle, Deceased demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-EIGHTH CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

534. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

535. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon him so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the Plaintiff Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

NINETY-NINTH CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

536. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

537. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

538. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the patients:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

539. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, Plaintiff Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle demands judgment in his favor against

defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDREDTH CAUSE OF ACTION

PLAINTIFF KATHLEEN C. WEDDLE VS. ALL DEFENDANTS

PUNITIVE DAMAGES

540. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

541. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, Plaintiff Patrick Admire, as Personal Representative of the Estate of Kathleen C. Weddle demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND FIRST CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

542. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

543. James Friesner suffered from melanoma and was advised of the opportunity to participate in the Trial through one of his caretakers.

544. On or about the __ day of _____, 19__, James Friesner met with Dr. McGee to discuss his participation in the Trial and the informed consent document.

545. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Mr. Friesner to participate.

546. As a result of being injected with the Vaccine and the GM-CSF, James Friesner suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression; James Friesner died on the ___ day of _____, 2000, ___ weeks after enrolling in the Trial; his death was not reported as an adverse event to anyone.

547. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

548. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND SECOND CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

549. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

550. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

551. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND THIRD CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

552. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

553. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

554. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of his constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to his great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff James Friesner demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND FOURTH CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

555. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

556. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

557. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

558. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

559. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

560. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff James Friesner demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND FIFTH CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

561. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

562. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

563. The conduct of defendants in making false statements to plaintiff knowing he would rely on these statements in determining whether he should participate in the Trial has caused emotional harm and was extreme and outrageous.

564. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND SIXTH CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

565. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

566. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

567. The misrepresentations set forth above were done with the knowledge that they were false when made.

568. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

569. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to his detriment.

WHEREFORE, for the above-stated reasons, plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND SEVENTH CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

570. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

571. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining him in order to determine his condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

572. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

573. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians,

nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the patient of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

574. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

575. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

576. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

577. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to his, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

WHEREFORE, for the above-stated reasons, plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND EIGHTH CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

578. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

579. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon him so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND NINTH CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

580. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

581. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

582. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

583. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND TENTH CAUSE OF ACTION

PLAINTIFF JAMES FRIESNER VS. ALL DEFENDANTS

PUNITIVE DAMAGES

584. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

585. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff.

WHEREFORE, for the above-stated reasons, Plaintiff James Friesner demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND ELEVENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

586. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

587. Terrell Grubbs suffered from melanoma and was advised of the opportunity to participate in the Trial through one of his caretakers.

588. On or about the __ day of _____, 1999, Terrell Grubbs met with Dr. McGee to discuss his participation in the Trial and the informed consent document.

589. In that meeting, Dr. McGee misrepresented the focus, purpose and scope of the Trial as set forth above and otherwise induced Mr. Grubbs to participate.

590. As a result of being injected with the Vaccine and the GM-CSF, Terrell Grubbs suffered severe and debilitating injuries, including but not limited to rashes, swelling, headaches, pain, nausea and depression, and his adverse reactions were not reported as adverse events to anyone.

591. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiff to be treated with dignity.

592. As a result of defendants' actions, plaintiff has suffered damages.

WHEREFORE, for the above-stated reasons, plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND TWELFTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

21 CFR §210, 211/21 CFR §601, 610/45 CFR §46

593. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

594. 45 CFR§46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T.

595. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff .

WHEREFORE, for the above-stated reasons, plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND THIRTEENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

42 U.S.C. §1983/CIVIL RIGHTS

596. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

597. The IRB Defendants and the State Actor Defendants at all times material to the allegations in the Complaint were acting under the authority of their offices with the University of Oklahoma and under the color and the laws of the State of Oklahoma.

598. As set forth above, the IRB Defendants and the State Actor Defendants under color of State Law deprived plaintiff of his constitutional rights to liberty, to be treated with dignity and to privacy all without due process of law to his great detriment and damage.

WHEREFORE, for the above-stated reasons, the plaintiff Terrell Grubbs demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND FOURTEENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

THE BELMONT REPORT

Breach of the Assurance Agreement

599. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

600. On or about November 20, 1996, Dr. Wortham, on behalf of OUHSC-Tulsa agreed that "all human research" at OUHSC-Tulsa would be "conducted in accordance with . . . the Belmont Report . . .."

601. This agreement is contained in a document known as the "Multiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

602. This Assurance Agreement in essence is a contract between OUHSC-Tulsa and the Department of Health and Human Services; plaintiff participants were third party beneficiaries to

this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at OUHSC-Tulsa.

603. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR§46.

604. As a result of this breach, plaintiff has suffered damages as set forth above.

WHEREFORE, for the above-stated reasons, the plaintiff Terrell Grubbs demands judgment in his favor against the defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND FIFTEENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

605. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

606. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused plaintiff severe emotional distress.

607. The conduct of defendants in making false statements to plaintiff knowing he would rely on these statements in determining whether he should participate in the Trial has caused emotional harm and was extreme and outrageous.

608. Plaintiff suffered severe emotional distress as a result of the conduct of the defendants.

WHEREFORE, for the above-stated reasons, plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND SIXTEENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. STATE ACTOR DEFENDANTS, IRB DEFENDANTS AND SPONSOR DEFENDANTS

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

609. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

610. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

611. The misrepresentations set forth above were done with the knowledge that they were false when made.

612. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decisions to participate and continue in the Trial.

613. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff participated and continued in the Trial to his detriment.

WHEREFORE, for the above-stated reasons, plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND SEVENTEENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. DR. MCGEE, ST. JOHN MEDICAL CENTER, IRB DEFENDANTS, AND DR. DONOVAN

NEGLIGENCE

614. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

615. At all times mentioned herein and material hereto, defendants Dr. McGee and St. John Medical Center ("Treating Defendants") and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to plaintiff of properly and carefully examining him in order to determine his condition and eligibility for the Trial, of properly and carefully administering the Trial protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

616. As a result of the careless, negligent and reckless conduct, plaintiff was caused to suffer pain, discomfort and damage.

617. Treating Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate the plaintiff's condition and eligibility for the Trial;

b. failing to perform proper and adequate testing for the plaintiff's condition;

c. failing to properly and adequately treat the plaintiff's condition;

d. failing to properly and adequately care for the plaintiff's condition;

e. failing to provide and afford proper and careful medical care and treatment;

f. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which Treating Defendants practiced at the time;

g. failing to properly care for the plaintiff's condition under all of the circumstances;

h. caring for the plaintiff in a negligent and improper manner;

i. failing to properly monitor the plaintiff's condition during the Trial;

j. failing to use a proper, adequate and safe Vaccine during the Trial;

k. failing to inform the patient of all the risks of performing the Trial so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

l. failing to properly and timely observe, discover, diagnose, treat and care for the plaintiff's condition;

m. failing to conform to the standard of care and treatment prevailing in the medical community in which Treating Defendants practiced at the time in conducting the Trial;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which Treating Defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

618. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of Treating Defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the Treating Defendants, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition,

as plaintiff had been led to believe there was a cure for his disease and that defendants would administer the cure to him, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

619. The IRB Defendants together, and each of them respectively, jointly and severally were careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures of IRBs;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

620. Defendant Dr. Donovan was careless, negligent and reckless in:

a. failing to exercise reasonable care under all of the circumstances, in accordance with accepted bioethical practices ;

b. failing to follow and abide by guidelines set forth by various governmental agencies; and

c. acting negligently per se.

621. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of IRB Defendants and Dr. Donovan, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff sustained serious personal injuries. As a result of participating in the Trial and based upon the negligence of the IRB Defendants and Dr. Donovan, plaintiff has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his loss and detriment. In addition, as plaintiff had been led to believe there was a cure for his disease and

that defendants would administer the cure to his, plaintiff lost time to perform all of his usual duties, occupation, recreational activities and avocation and has been prevented from coming to terms with his disease.

WHEREFORE, for the above-stated reasons, plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND EIGHTEENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. DR. MCGEE AND ST. JOHN MEDICAL CENTER

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

622. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

623. Defendants, and each of them respectively, failed to inform the plaintiff of the risks of all treatment, care, therapy and procedures performed upon him so as to afford the plaintiff the opportunity to make an informed decision as to the performance of said procedures; thus the injections plaintiff received constituted a battery.

WHEREFORE, for the above-stated reasons, the plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND NINETEENTH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. DR. MCGEE, IMMUNEX, ST. JOHN MEDICAL CENTER AND HOAG CANCER CENTER

STRICT PRODUCTS LIABILITY

624. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

625. Defendants Dr. McGee, St. John Medical Center, Immunex and Hoag Cancer Center designed, manufactured and supplied the Vaccine and GM-CSF which caused great physical and emotional damage to the plaintiff.

626. Defendants breached their duties and obligations to the plaintiff by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

627. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries to the plaintiff.

WHEREFORE, for the above-stated reasons, plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND TWENTIETH CAUSE OF ACTION

PLAINTIFF TERRELL GRUBBS VS. ALL DEFENDANTS

PUNITIVE DAMAGES

628. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

629. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff .

WHEREFORE, for the above-stated reasons, Plaintiff Terrell Grubbs demands judgment in his favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND TWENTY-FIRST CAUSE OF ACTION

LIVING PLAINTIFF PARTICIPANTS AND PLAINTIFF

SYDNEE ROBERTSON VS. ALL DEFENDANTS

MEDICAL MONITORING

630. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

631. As a result of the above described acts, all the living Plaintiff Participants and plaintiff Sydnee Robertson are at increased risk of disease and harm.

632. A program of medical monitoring will be beneficial to the early detection of any such disease or harm so as to increase the likelihood of reducing any resulting damage or injury.

WHEREFORE, for the above-stated reasons, each of the plaintiffs demand judgment in their favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

ONE HUNDRED AND TWENTY-SECOND CAUSE OF ACTION

SPOUSE PLAINTIFFS VS. DEFENDANTS

633. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

634. Plaintiffs Stephen Robertson, Paige Teel, Julie Horn, Wesley Butler, Lester Harris and Bob Rogers, Phyllis Friesner and Sandra Grubbs ("Plaintiff Spouses") are the spouses of Plaintiff Participants.

635. As a direct and proximate result of the actions described above of all defendants named herein, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, Plaintiff Spouses have in the past been and will in the future continue to be deprived of the earnings, comfort, society and companionship of their said spouses, all to their great loss and detriment.

636. As a direct and proximate result of the foregoing, Plaintiff Spouses suffered, and are suffering for an indefinite period of time in the future, damages, injuries and losses, including but not limited to, a loss of financial support, and the Plaintiff Spouses have been wrongfully deprived of the contributions they would have received from Plaintiff Participants, including monies which Plaintiff Participants would have provided for such items as clothing, shelter, food, medical care and education.

637. As a direct and proximate result of the foregoing, Plaintiff Spouses would have been, continue to be and will be in the future wrongfully deprived of large and various sums of money which Plaintiff Participants would have contributed to their support.

638. As a direct and proximate result of the foregoing, Plaintiff Spouses incurred or have been caused to incur and paid large and various expenses for Plaintiff Participants' treatment and well being, directly attributable to defendants' actions and inactions.

639. Plaintiff Spouses make claim for the loss of love, affection, services, earnings, support and all other damages recoverable.

WHEREFORE, for the above-stated reasons, each of the Plaintiff Spouses demand judgment in their favor against defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), attorneys' fees, interest and costs of suit.

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"ATTORNEY'S LIEN CLAIMED"
"JURY TRIAL DEMANDED"